

**REMARKS**

In the Office Action dated November 7, 2003, claims 12-22 are pending, claims 12-20 and 22 are rejected, objection is made to claim 21, and the rejection is made final. Applicants appreciate the indication of allowable subject matter at least in claim 21. Reconsideration is requested for at least the reasons discussed hereinbelow.

Claim 21 is submitted in independent form in view of the indication of allowability. Claim 12 is amended to more particularly point out and distinctly claim the subject matter regarded as invention. No new matter is added. Amended claim 12 has no change in scope.

Claims 12-19 are rejected under 35 U.S.C. §103(a) over Metz-Stavenagen, et al. (Metz; U.S. 6,074,391). The Examiner has concluded that cage 106 of Metz is the head of the screw of the Metz anchoring element. Applicants' strongly disagree.

However, the enclosed analysis of elements of claim 12 with respect to Metz is made under the assumption that the head of the screw of Metz anchoring element is the cage 106, as set forth by the Examiner. See enclosed Table comparing the elements of claim 12 with the disclosure of Metz.

From the Table, it can be seen that the anchoring element of Metz-Stavenhagen **fails** to have the elements f), i) and j), namely,

wherein the screw comprises a threaded section and a **head having a spherical segment-shaped section**;

wherein the receiving portion comprises a first end, a second end opposite the first end, a longitudinal axis passing through the two ends, a bore

coaxial with the longitudinal axis, a first region adjoining the first end with an essentially U-shaped cross-section with two free arms for receiving the rod (19) to be inserted, the two free arms comprising a thread, **a second region adjoining the second end for receiving the spherical segment-shaped section of said head; and**

**wherein the thread section and the spherical segment-shaped section of the head of the screw are separate parts**

as set forth in claim 12.

It should be noted that the spherical bearing surface 124 at the inner wall of cage 106, which encompasses the spherical shaped section 102 [i.e., the head] of the shank (col. 6, l. 29-31), is not spherical **segment**-shaped, because it is hollow.

The Examiner acknowledges in the office action that Metz lacks the use of a spherical head and shank but he is of the opinion that it would have been an obvious design choice to have modified Metz, because Applicants allegedly have not disclosed that having the spherical head and a shank solves any particular problem or is of any particular purpose.

This is not the case. On page 1, 2<sup>nd</sup> par. of the application, Applicants state that the surgeon always needs different length of the of the screw. For one surgery a plurality of anchoring elements are needed with screws having different length according to the place of application. Therefore, a considerable stockpile of screws having different length is required resulting in increased costs.

This problem is also present with the anchoring element of Metz. Because the shank 100 and its spherical end part 102 are formed as one piece, a plurality of such shanks in different length and even a plurality of pre-mounted pedicle screws (shank plus cage 106 and receiver part 108) have to be stocked for each surgery, because the surgeon does not know exactly in advance how many pedicle screws with which length is needed.

This problem is solved by anchoring elements according to the present invention wherein the threaded section of the straw and the spherical segment shaped portion of the head are separate parts. Thus, with the anchoring elements of the present invention, it is possible to first screw into the bone the threaded section 14, i.e. the shank, and then to shorten the shank to a desired length by the surgeon (p. 7, 2<sup>nd</sup> par. of the application). Then, the receiving portion 1 is placed onto the shank and thereafter the spherical segment-shaped head 15 is introduced into the receiving portion and connected to the shank. Next, the receiving portion is connected to a rod. In this state, it is still possible to adjust the angular position of the shank with respect to the receiving portion because the spherical segment-shaped section of the head is pivotable in the receiving portion. After fixing the pressure element, the angular position is fixed.

As stated on page 2, 2<sup>nd</sup> par. of the application, as a result thereof, the maintenance of stocks of anchoring elements can be substantially reduced and, at the same time, the possibilities of the surgeon to make finer adjustments concerning the length of the screws are increased.

Metz **fails** to solve this problem. Nor does Metz gives any hint of a suggestion for arriving at the presently claimed solution to this problem. Thus, it is not seen how the present invention would have been obvious to one of ordinary skill in the art in view of Metz.

Claims 20 and 22 are rejected under 35 U.S.C. §103(a) over Metz in view of Brumfield et al. (U.S. 5,527,314). Metz is discussed in detail above. Brumfield does not make up for any of the deficiencies of Metz. For example, Brumfield also fails to teach or suggest an anchoring element

wherein the screw comprises a threaded section and a **head having a spherical segment-shaped section**;

wherein the receiving portion comprises a first end, a second end opposite the first end, a longitudinal axis passing through the two ends, a bore coaxial with the longitudinal axis, a first region adjoining the first end with an

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essentially U-shaped cross-section with two free arms for receiving the rod (19) to be inserted, the two free arms comprising a thread, **a second region adjoining the second end for receiving the spherical segment-shaped section of said head; and**  
**wherein the thread section and the spherical segment-shaped section of the head of the screw are separate parts**

as set forth in claim 12.

Thus, it is not seen how the present invention would have been obvious to one of ordinary skill in the art in view of any combination of Metz and Brumfield.

All claims being allowable, it is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,

Date: January 6, 2004

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col. – column; 1. = line

<b>Claim</b>	<b>Elements</b>	<b>Metz, Stavenhagen US 6,074,391 Figs. 10-14</b>
12	a) Anchoring element.	col. 5, 1. 67 pedicle screw
	b) The anchoring element comprises a screw.	col. 6, 1.1 screw shank (100)
	c) The anchoring element comprises a receiving portion for connecting the screw to a rod.	col. 6, 1.8 receiving part (108)
	d) The screw comprises a threaded section.	col. 6, 1. 1-2 Fig. 11 (100)
	e) The screw comprises a head.	Fig. 11 col. 6, 1.6 cage (106)
	f) The head has a spherical segment shaped portion.	N/A
	g) The receiving portion comprises a first end, a second end opposite the first end, a bore coaxial with the longitudinal axis.	Fig. 10 (108)
	h) The receiving portion comprises a first region adjoining the first end with an essentially U-shaped cross-section with two free arms for receiving the rod to be inserted, the two free arms comprising a thread.	Fig. 10 (108, 110)
	i) The receiving portion comprises a second region adjoining the second end for receiving the spherical segment-shaped section of said head.	N/A
	j) The anchoring element comprises an element which exerts pressure on the rod or on the head.	Fig. 11 col. 6, 1. 33-39, screw (126)
	k) The thread section and the <u>spherical segment-shaped section of the head</u> of the screw are separate parts.	N/A